

Appl. No. 09/297,181
Reply and Amendment dated Sept. 12, 2003
Reply to Office Action of Mar. 12, 2003

Remarks

Applicants request entry of the amendments and reexamination of the application. On even date, applicants submit a Request for Extension of Time and fee.

Applicants have amended claim 55. The sequences recited in claim 55 are disclosed in the specification. Applicants also add new claims 61-63. The new claims recite a fragment of the antibody disclosed in the specification. The fragments have obvious utility in binding to p53 proteins, as shown in the Examples and accompanying Figures. Furthermore, the amino acid sequences of the fragments have been disclosed in the specification's Sequence Listing. Since the new claims recite the antibody of the elected claims, and any search of the antibody would necessarily encompass the fact that the antibody is a polypeptide that comprises an amino acid sequence, applicants submit that the new claims fall within the elected group of claims.

No new matter enters by the amendments to this application.

Initially, Applicants request an Examiner's Interview. Applicants' representative will contact the Examiner after the filing of this paper to arrange a convenient date.

Oath or Declaration

An executed Declaration is submitted herewith. The Declaration identifies the foreign applications on which applicants claim priority and the specification of this application. This application was originally filed as a § 371 application.

Rejection under 35 U.S.C. § 101

Claims 55 and 60 stand rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter.

As suggested by the Examiner, claim 55 has been amended to recite a "purified antibody." The new claims recite a fragment of an antibody, which is also statutory subject matter.

This rejection should be withdrawn.

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Rejection under 35 U.S.C. § 112

Claims 55 and 60 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable one to make and use the invention.

Claim 55 has been amended to recite a purified antibody 11D3. A method for making an antibody like 11D3 is clearly disclosed in Example 1, at page 25 of the specification. Applicants submit that one of ordinary skill in the art is clearly capable of using the disclosure in Example 1, together with what one of ordinary skill in the art knows about producing antibodies, to make an antibody as claimed. Furthermore, applicants have demonstrated the use of such antibodies in detecting the presence of p53 (see Example 4 and Figure 5, for example). Thus, one of skill in the art can readily make and use the claimed antibody.

Furthermore, the same Example 1 details that p53 fragments were used to produce an antibody. A subset of the antibodies produced clearly bind p53 protein, as shown in Figures 2 and 3 and explained in Example 1. These well known experiments sufficiently demonstrate the binding of the antibodies to a p53 protein, and a specific mutant also. One of skill in the art would need no further explanation or showing to make and use the claimed antibody.

The new claims recite antibody fragments where the applicants have disclosed the exemplary amino acid sequences. Therefore, one of ordinary skill in the art would be able to make and use the claimed invention from the disclosure of these amino acid sequences and their use in recognizing p53 proteins shown in the Examples (see Example 4).

For these reasons, applicants request withdrawal of this rejection.

Deposit Requirement

As stated above, Example 1 details the method to produce the claimed antibody. The Examiner does not discuss the presence of this Example in the rejection. Applicants request clarification of why a deposit would be required when the steps to produce the antibody are disclosed in the specification. A deposit may be required if no other means for making the antibody exist. In this case, applicants have also disclosed the amino acid

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sequence that comprises the binding portion of the antibody. One of ordinary skill in the art is familiar with methods of manipulating antibody fragments. Therefore, one of ordinary skill in the art could produce an 11D3 antibody by recombining the binding region with a crystallizable region of an antibody. No deposit would be required to make this antibody since the sequence is given in the specification.

Applicants request reconsideration and withdrawal of the Deposit requirement.

Rejection under 35 U.S.C. § 112

Claims 55 and 60 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly fails to convey that the inventors had possession of the claimed invention at the time the application was filed.

Claim 55 has been amended to remove the recitation of variant and insert the amino acid sequence of the variable region of the antibody. Applicants' specification clearly discloses the possession of the claimed antibody of the amended claims since the methods for making the antibody and the amino acids sequence for the binding region of the antibody is disclosed in the specification.

Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 55 and 60 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claim 55 has been amended to remove the recitation "the same epitope." This rejection should be withdrawn.

The application is in condition for allowance. Timely notification of allowability is requested.

If there are any additional fees due with the filing of this document, including fees for the net addition of claims, applicants respectfully request that any and all fees be charged to Deposit Account No. 50-1129. If any extension of time request or any petition is required for the entry of this paper or any of the accompanying papers, applicants hereby petition or

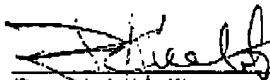
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request the extension necessary. The undersigned authorizes any fee payment from
Deposit Account No. 50-1129.

Respectfully submitted,
Wiley Rein & Fielding LLP

Date: September 12, 2003

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